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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/542,935	04/04/2000	Maria Palasis	02844/56301	5876
26646	7590	12/08/2006	EXAMINER	
KENYON & KENYON LLP ONE BROADWAY NEW YORK, NY 10004			WHITEMAN, BRIAN A	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 12/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

09/542,935

Applicant(s)

PALASIS, MARIA

Examiner

Brian Whiteman

Art Unit

1635

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 14 November 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☒ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: None.

Claim(s) objected to: None.

Claim(s) rejected: 60, 62 and 65-91.

Claim(s) withdrawn from consideration: None.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.

12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____

13. ☐ Other: _____.

P. H.

Continuation of 11. does NOT place the application in condition for allowance because: The amendment cannot be entered because the claims are not in compliance with 37 CFR 1.121. It is noted that the claims are listed as an appendix, but it is not apparent if the claims should be the claims of record and supplement any pending claim set. To expedite prosecution, the applicant's argument will be addressed. In view of the lengthy prosecution history of the instant application, the majority of applicant's arguments have already been addressed in a prior office action.

Priority:

In response to applicant's argument that the instant claims have support in the US patent '039 (see column 5, line 49 to column 6, line 22), the argument has already been addressed in the final rejection (pages 2-5) mailed on 8/15/06. More specifically, the specification contemplates using either a nucleic acid or a protein not both.

In response to applicant's argument that column 4, line 64 to column 5, line 48 of '039 provides support for the claims, the argument is not found persuasive because column 4, line 64 to column 5, line 48 is directed to a number of generic compounds including antisense, nucleic acids, pharmaceutically active compounds, ribozymes, proteins, and agents. There is nothing in this paragraph that would lead one skilled in the art to products recited in the instant claims. Thus, instant claims do not enjoy priority to application 09/204,254 now US 6,369,039.

New Matter Rejection:

In response to applicant's argument that page 5, lines 3-11 provide support for the instant claims, the argument is not found persuasive because as pointed out by applicant, the instant claims limit the first therapeutic agent to a polynucleotide encoding an angiogenic agent and second therapeutic agent to an angiogenic agent.

In response to applicant's argument that page 18, line 1 provides support for the limitation missing on page 5, lines 3-11, the argument is not found persuasive because page 18, line 1 generically recites angiogenic agents and does not lead the skilled artisan to using an angiogenic protein with a polynucleotide encoding an angiogenic agent.

In response to applicant's argument that original claim 33, provides support for the instant claims, the argument is not found persuasive for the reasons of record and has already been addressed in the a previous office action (see office action page 6, mailed on 3/6/06).

In response to applicant's argument that page 22, line 21 to page 23, line 6 of the instant specification provides support for the instant claims, the argument is not found persuasive because there is nothing recited in the passage that would lead the skilled artisan to claimed product.

In response to applicant's argument that Example 7, pages 28-29 provide using two angiogenic agents, the argument is not found persuasive because while it is acknowledged that Example 7 uses two angiogenic agents, the agents are both polynucleotides. The working example does not lead the skilled artisan to using a polynucleotide with a protein.

In response to applicant's argument that page 5, lines 6-7 and page 6, line 9 in combination with page 17, lines 6-8 provide support for the instant claims, the argument is not found persuasive because the applicant page 5 and 6 recite a generic polynucleotide and page 17 recites a genus of non-genetic materials. There is on these passages that would the skilled artisan to the claimed product.

103 rejection:

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). This is the case here. In response to applicant's argument that Roth does not disclose the limitation 'polymeric coating comprising an angiogenic agent and a polynucleotide encoding an angiogenic agent', the argument is not found persuasive because the combination of Donovan and Crystal teach polymeric coating comprising a polynucleotide encoding angiogenic protein and an angiogenic protein.

In response to applicant's argument that Donovan does not teach a polymeric coating on a stent, the argument is not found persuasive because applicant is arguing against the references individually (*In re Keller*). Furthermore, the only claims that recite stent are claims 69, 70, 84, and 85 and the rest of the claims do not recite stent. Donovan teaches a microparticle (allowing controlled release of biologically active substance) comprising a polymer and a biologically active substance (columns 16-18), which reads on the structure recited in claims 60, 62, 65-68, 71-83, and 86-89.

The argument against Roth taken with Crystal in further view of either Donovan or Branellec are based on the same arguments against Roth taken with Crystal and are not found persuasive for the reasons of record.

**Notice of Non-Compliant
Amendment (37 CFR 1.121)**

Application No.

09/542,935

Examiner

Brian Whiteman

Applicant(s)

PALASIS, MARIA

Art Unit

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The amendment document filed on 14 November 2006 is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121 or 1.4. In order for the amendment document to be compliant, correction of the following item(s) is required.

THE FOLLOWING MARKED (X) ITEM(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT:

- ☐ 1. Amendments to the specification:
- ☐ A. Amended paragraph(s) do not include markings.
 - ☐ B. New paragraph(s) should not be underlined.
 - ☐ C. Other _____.
- ☐ 2. Abstract:
- ☐ A. Not presented on a separate sheet. 37 CFR 1.72.
 - ☐ B. Other _____.
- ☐ 3. Amendments to the drawings:
- ☐ A. The drawings are not properly identified in the top margin as "Replacement Sheet," "New Sheet," or "Annotated Sheet" as required by 37 CFR 1.121(d).
 - ☐ B. The practice of submitting proposed drawing correction has been eliminated. Replacement drawings showing amended figures, without markings, in compliance with 37 CFR 1.84 are required.
 - ☐ C. Other _____.
- ☒ 4. Amendments to the claims:
- ☐ A. A complete listing of all of the claims is not present.
 - ☐ B. The listing of claims does not include the text of all pending claims (including withdrawn claims)
 - ☒ C. Each claim has not been provided with the proper status identifier, and as such, the individual status of each claim cannot be identified. Note: the status of every claim must be indicated after its claim number by using one of the following status identifiers: (Original), (Currently amended), (Canceled), (Previously presented), (New), (Not entered), (Withdrawn) and (Withdrawn-currently amended).
 - ☐ D. The claims of this amendment paper have not been presented in ascending numerical order.
 - ☐ E. Other: _____.
- ☐ 5. Other (e.g., the amendment is unsigned or not signed in accordance with 37 CFR 1.4):

For further explanation of the amendment format required by 37 CFR 1.121, see MPEP § 714.

TIME PERIODS FOR FILING A REPLY TO THIS NOTICE:

1. Applicant is given **no new time period** if the non-compliant amendment is an after-final amendment or an amendment filed after allowance. If applicant wishes to resubmit the non-compliant after-final amendment with corrections, the **entire corrected amendment** must be resubmitted.
2. Applicant is given **one month**, or thirty (30) days, whichever is longer, from the mail date of this notice to supply the correction, if the non-compliant amendment is one of the following: a preliminary amendment, a non-final amendment (including a submission for a request for continued examination (RCE) under 37 CFR 1.114), a supplemental amendment filed within a suspension period under 37 CFR 1.103(a) or (c), and an amendment filed in response to a *Quayle* action. If any of above boxes 1. to 4. are checked, the correction required is only the **corrected section** of the non-compliant amendment in compliance with 37 CFR 1.121.

Extensions of time are available under 37 CFR 1.136(a) only if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action.

Failure to timely respond to this notice will result in:

Abandonment of the application if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action; or

Non-entry of the amendment if the non-compliant amendment is a preliminary amendment or supplemental amendment.



Legal Instruments Examiner (LIE), if applicable

Telephone No.